HOUSE BILL NO. 394

INTRODUCED BY D. MCALPIN

A BILL FOR AN ACT ENTITLED: "AN ACT PROHIBITING THE USE OF INDIVIDUALLY IDENTIFIED PRESCRIBING INFORMATION FOR MARKETING PURPOSES; PROVIDING DEFINITIONS; PROVIDING PENALTIES; AMENDING SECTIONS 2-18-702, 33-1-111, 53-4-1010, 53-6-115, 53-6-1010, AND 53-6-1005, MCA; AND PROVIDING A TERMINATION DATE."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Legislative purpose.** (1) It is the purpose of the legislature to safeguard the confidentiality of prescribing information, protect the integrity of the relationship between a health care provider and the provider's patient, maintain the integrity of and public trust in the medical profession, restrain undue influence by pharmaceutical industry marketing representatives over a health care provider's prescribing decisions, and further the state's interest in improving the quality of and lowering the costs of health care.

(2) The legislature intends to regulate the monitoring of health care prescribing practices only as the monitoring relates to commercial marketing by companies that sell prescription drugs and devices. The legislature does not intend to regulate the monitoring of prescribing practices for other purposes, such as quality control, research unrelated to marketing, or uses by government agencies or other entities that do not sell health care products.

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through ~~7~~ 6], the following definitions apply:

(1) "DEVICE" MEANS ANY INSTRUMENT, APPARATUS, OR CONTRIVANCE INTENDED:

(A) FOR USE IN THE DIAGNOSIS, CURE, MITIGATION, TREATMENT, OR PREVENTION OF DISEASE IN HUMANS; OR

(B) TO AFFECT THE STRUCTURE OR ANY FUNCTION OF THE HUMAN BODY.

~~(1)~~(2) "Individual identifying information" means information that directly or indirectly identifies a prescriber or a patient in this state when the information is from or relates to a prescription drug order or a prescription drug or device.

~~(2)~~(3) "Marketing" means an activity by a company making or selling a prescription drug or device or by

a company's agent that is intended to influence prescribing or purchasing choices involving the company's products. The term includes but is not limited to:

(a) advertising, publicizing, promoting, or sharing information about a prescription drug or device;

(b) identifying individuals to receive a message promoting the use of a particular prescription drug or device, including but not limited to an advertisement, brochure, or contact by a sales representative;

(c) planning the substance of a sales representative's visit or communication or the substance of an advertisement or other promotional message or document;

(d) evaluating or compensating sales representatives;

(e) identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation, or employment of value; or

(f) advertising or promoting a prescription drug or device directly to a patient.

(4) "PATIENT" MEANS AN INDIVIDUAL WHO RECEIVES OR HAS RECEIVED HEALTH CARE.

(5) "PRESCRIBER" MEANS A MEDICAL PRACTITIONER, AS DEFINED IN 37-2-101, LICENSED UNDER THE PROFESSIONAL LAWS OF THIS STATE TO ADMINISTER AND PRESCRIBE MEDICINE AND DRUGS.

(6) "PRESCRIPTION DRUG" MEANS ANY DRUG THAT IS REQUIRED BY FEDERAL LAW OR REGULATION TO BE DISPENSED ONLY BY A PRESCRIPTION SUBJECT TO SECTION 503(B) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 353).

(7) "PRESCRIPTION DRUG ORDER" HAS THE MEANING PROVIDED IN 37-7-101.

~~(3)~~(8) "Regulated record" means information or documentation from a prescription drug order written by a prescriber doing business in this state or from a prescription drug or device dispensed in this state.

NEW SECTION. **Section 3. Privacy provisions for prescription drug order information.** (1) A person may not knowingly disclose or use a regulated record in this state for marketing a prescription drug or device if the record includes prescription information containing individual identifying information.

(2) A regulated record containing individual identifying information may be transferred to another entity, including another branch or subsidiary of the same firm, only if satisfactory assurance exists that the recipient will prevent the record from being disclosed or used in this state for a marketing purpose prohibited under this section.

(3) (A) Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged, or used for nonmarketing purposes.

(B) NONMARKETING PURPOSES INCLUDE BUT ARE NOT LIMITED TO:

(I) EFFORTS BY A HEALTH PLAN OR BENEFITS MANAGEMENT PROGRAM TO ENSURE COMPLIANCE WITH AN INDEPENDENTLY ESTABLISHED FORMULARY BASED ON EVIDENCE-BASED PRESCRIBING GUIDELINES AND COST CONTAINMENT GOALS;

(II) EDUCATIONAL OR QUALITY ASSURANCE PROGRAMS DESIGNED FOR INDIVIDUALS COVERED BY A HEALTH PLAN OR BENEFITS MANAGEMENT PROGRAM;

(III) COMMUNICATION BY A PHARMACIST ABOUT ISSUES RELATED TO PATIENT SAFETY, GENERIC SUBSTITUTION, OR QUESTIONS FROM A PATIENT ABOUT A PRESCRIPTION DRUG; OR

(IV) ANY COMMUNICATION ABOUT SAFETY WARNINGS, ADVERSE EVENT REPORTING, LABELING CHANGES, OR COMPLIANCE WITH FEDERAL RISK EVALUATION AND MITIGATION STRATEGIES.

(4) This section does not prohibit the collection, use, transfer, or sale of regulated records for marketing purposes if:

(a) the data is aggregated;

(b) the data does not contain individual identifying information; and

(c) there is no reasonable basis to believe that the data may be used to obtain individual identifying information.

(5) This section does not prevent a person from disclosing individual identifying information to the identified individual. The disclosed information may not include protected information pertaining to any other person.

(6) The provisions of [sections 1 through ~~7~~ 6] apply to prescription drug information held by a state agency or a political subdivision of the state through a state health care program, including but not limited to:

(a) health care services provided to individuals in the custody or supervision of the state;

(b) a health insurance program for public employees or retirees operated under Title 2, chapter 18;

(c) the state children's health insurance program provided for in Title 53, chapter 4, part 10;

(d) the state medicaid program provided for in Title 53, chapter 6; and

(e) a state pharmaceutical assistance program, including the prescription drug plus discount program and the pharmacy access program provided for in Title 53, chapter 6, part 10.

NEW SECTION. **Section 4. Penalties.** (1) A person who knowingly fails to comply with the requirements of [sections 1 through ~~7~~ 6] by using or disclosing regulated records in a manner not authorized in

[sections 1 through ~~7~~ 6] is subject to ~~an administrative~~ A CIVIL penalty of at least $10,000 and not more than $50,000 for each violation~~, as assessed by the department~~.

(2) Each disclosure of a regulated record constitutes a violation under this section.

(3) AN AGENCY THAT REGULATES, LICENSES, CERTIFIES, OR REGISTERS A PERSON WHO KNOWINGLY FAILS TO COMPLY WITH THE REQUIREMENTS OF [SECTIONS 1 THROUGH 7] MAY SEEK ADMINISTRATIVE RELIEF AS PROVIDED BY LAW.

~~(3)~~(4) In addition to any other remedy provided by law, a violation of [sections 1 through ~~7~~ 6] is an unfair or deceptive act in trade or commerce and an unfair method of competition and may be enforced through the Montana Unfair Trade Practices and Consumer Protection Act of 1973 provided for in Title 30, chapter 14.

~~NEW SECTION. **Section 5. Rulemaking authority.** The board may adopt rules as necessary to implement the provisions of [sections 1 through 7].~~

NEW SECTION. **Section 5. No effect on truthful speech to doctors or patients.** Nothing in [sections 1 through ~~7~~ 6] may be interpreted to regulate the content, time, place, or manner of a discussion between a prescriber and the prescriber's patient or a prescriber and a person representing a manufacturer of a prescription drug or device.

NEW SECTION. **Section 6. No extraterritorial effect.** Nothing in [sections 1 through ~~7~~ 6] may be interpreted to regulate conduct that takes place entirely outside of this state.

Section 7. Section 2-18-702, MCA, is amended to read:

"2-18-702. Group insurance for public employees and officers. (1) (a) Except as provided in subsection (1)(c), all counties, cities, towns, school districts, and the board of regents shall upon approval by two-thirds vote of their respective officers and employees enter into group hospitalization, medical, health, including long-term disability, accident, or group life insurance contracts or plans for the benefit of their officers and employees and their dependents. The laws prohibiting discrimination on the basis of marital status in Title 49 do not prohibit bona fide group insurance plans from providing greater or additional contributions for insurance benefits to employees with dependents than to employees without dependents or with fewer dependents.

(b) The governing body of a county, city, or town may, at its discretion, consider the employees of private, nonprofit economic development organizations to be employees of the county, city, or town solely for the

purpose of participation in group hospitalization, medical, health, including long-term disability, accident, or group life insurance contracts or plans as provided in subsection (1)(a). The governing body of the county, city, or town may require an employee or organization to pay the actual cost of coverage required for participation or may, at its discretion and subject to any restriction on who may be a member of a group, pay all or part of the cost of coverage of the employee of the organization.

(c) The governing body of a third, fourth, fifth, sixth, or seventh class county or the board of trustees of a hospital district may, at its discretion, exempt employees of a county hospital, county rest home, or hospital district from participation in group hospitalization, medical, health, including long-term disability, accident, or group life insurance contracts or plans provided pursuant to subsection (1)(a) or (1)(b).

(2) State employees and elected officials, as defined in 2-18-701, may participate in state employee group benefit plans as are provided for under part 8 of this chapter.

(3) For state officers and employees, the premiums required from time to time to maintain the insurance in force must be paid by the insured officers and employees, and the state treasurer shall deduct the premiums from the salary or wages of each officer or employee who elects to become insured, on the officer's or employee's written order, and issue a warrant for the premiums to the insurer.

(4) For the purpose of this section, the plans of health service corporations for defraying or assuming the cost of professional services of licentiates in the field of health or the services of hospitals, clinics, or sanitariums or both professional and hospital services must be construed as group insurance and the dues payable under the plans must be construed as premiums for group insurance.

(5) If the board of trustees of a school district implements a self-insured group health plan or if the board of regents implements an alternative to conventional insurance to provide group benefits to its employees, the board shall maintain the alternative plan on an actuarially sound basis.

(6) The state, a governing body, or a health insurance issuer operating a health plan under part 8 or this part shall comply with the provisions of [sections 1 through ~~7~~ 6]."

Section 8. Section 33-1-111, MCA, is amended to read:

"33-1-111. Eligibility requirements of health insurance issuers. (1) As a condition of doing business in the state of Montana, a health insurance issuer, a multiple employer welfare arrangement, a third-party administrator, a health maintenance organization, a pharmacy benefit manager, a health services corporation, or any other party that by statute, contract, or agreement is legally responsible for payment of a claim for a health

care item or service shall:

~~(1)~~(a) upon request, provide to the department of public health and human services eligibility information for individuals who are eligible for or receiving medicaid, including but not limited to:

~~(a)~~(i) data to determine during what period the medicaid recipient or medicaid-eligible individual or the spouse or dependents of the recipient or eligible individual may be or may have been covered by any of the entities listed in this section; and

~~(b)~~(ii) data regarding the nature of the coverage that is or was provided, including but not limited to the name, address, and identifying information of the entity providing coverage;

~~(2)~~(b) respond to any inquiry from the department of public health and human services regarding a claim for payment for any health care item or service submitted not later than 3 years after the date the item or service was provided;

~~(3)~~(c) accept the department of public health and human services' right of recovery and the assignment from the medicaid recipient to the department of public health and human services of any right of an individual or other entity to payment from any of the entities listed in this section for an item or service for which medicaid has paid; ~~and~~

~~(4)~~(d) agree not to deny a claim submitted by the department of public health and human services solely on the basis of the date of submission of the claim, the type or format of the claim form, or a failure to present proper documentation at the point of sale that is the basis of the claim if:

~~(a)~~(i) the claim is submitted by the department of public health and human services within the 3-year period beginning on the date on which the service or item was provided; and

~~(b)~~(ii) any action by the department of public health and human services to enforce its rights with respect to the claim is commenced within 6 years after the department submitted the claim~~.~~; and

(e) comply with the provisions of [sections 1 through ~~7~~ 6].

~~(5)~~(2) This section may not be construed to:

(a) require that a third party pay any department claim for services or items that are not covered under the applicable health care plan;

(b) require that any third-party administrator, fiscal intermediary, or other contractor pay a department claim from its own funds unless the entity also bears the financial obligation for the claim under the applicable plan documents;

(c) impose any liability on an entity to pay claims that the entity does not otherwise bear; or

(d) negate any right of indemnification against a plan sponsor or other entity with ultimate liability for health care claims by a third-party administrator, fiscal intermediary, or other contractor that pays the claims."

Section 9. Section 53-4-1010, MCA, is amended to read:

"53-4-1010. (Temporary) Sharing of information. (1) The department of public health and human services, health care providers, insurance companies, and other entities may share only health care information, medical records, income, and other participant eligibility information for the purposes of administering the program.

(2) (a) The limitations on disclosure of information provided in [sections 1 through ~~7~~ 6] apply to this part.

(b) The limitations on disclosure of information provided in 33-19-306 do not apply if they conflict with this part.

(3) To the extent possible, ~~the~~ information disclosed under this section may not be disclosed in a manner that would violate the privacy of an individual or be released to any entity that is not necessary for the administration of the program. (Terminates on occurrence of contingency--sec. 15, Ch. 571, L. 1999.)"

Section 10. Section 53-6-115, MCA, is amended to read:

"53-6-115. Contracts with other agencies. (1) The department of public health and human services may by suitable rules provide for contracting with any state or private agency for processing and payment of claims under the program of medical assistance, and the department may contract with one or more private or state agencies to provide any or all of the enumerated medical services.

(2) The department and any state or private agency with which it contracts under this section shall comply with the provisions of [sections 1 through ~~7~~ 6]."

Section 11. Section 53-6-1010, MCA, is amended to read:

"53-6-1010. Specifications for administration of program. (1) The department shall adopt specifications for the administration and management of the program. Specifications may include but are not limited to program objectives, accounting and handling practices, supervisory authority, and an evaluation methodology.

(2) Information disclosed by manufacturers during negotiations and all terms and conditions negotiated between the director and manufacturers and all information requested or required under the program are public

information, except for information that the department determines is proprietary information.

(3) The department may use a formulary or other committee to determine preferred drug lists for department programs. The department shall include a representative of consumers on any formulary committee or committee to determine preferred drug lists for purchase by the department or reimbursement of costs. Any formulary or preferred drug list must be based on objective clinical data on safety and effectiveness. If two or more drugs are found to be equally effective and safe for the treatment of the same medical condition, the drug available at the lowest net price, inclusive of discounts and rebates, must be placed on the list. Other drugs for treating the same medical condition may be added to the list if they are therapeutically equivalent and the department determines them to be cost-effective.

(4) The department may negotiate rebates from the prescription drug manufacturers for drugs that will be on any preferred drug list. The department may negotiate price discounts with prescription drug manufacturers for any state-purchased health care programs, including medicaid, the state children's health insurance program, and the program provided for in 53-6-1002.

(5) The department may use the access restrictions and a preferred drug list to negotiate for the most favorable discount prices and rebates for the program.

(6) The department may participate in multistate purchasing pool initiatives for the benefit of the program.

(7) The department and any entities with which it contracts pursuant to 53-6-1013 shall comply with the provisions of [sections 1 through ~~7~~ 6]. "

Section 12. Section 53-6-1005, MCA, is amended to read:

"53-6-1005. Department administration -- pharmacy access. (1) The department shall administer the pharmacy access program. The department shall provide for outreach and enrollment in the pharmacy access program. The department shall integrate the enrollment and outreach procedures with other services provided to individuals and families eligible for other related programs.

(2) The department shall report on Montana's prescription drug use, needs, and trends and submit a report with recommendations to the governor and to the legislature by September 15, 2006.

(3) The department and any entities with which it contracts for operation of the pharmacy access program shall comply with the provisions of [sections 1 through ~~7~~ 6]."

NEW SECTION. **Section 13. Codification instruction.** [Sections 1 through ~~7~~ 6] are intended to be

codified as an integral part of ~~Title 37, chapter 7, part 4,~~ TITLE 50, CHAPTER 4, and the provisions of ~~Title 37, chapter 7,~~ TITLE 50, CHAPTER 4, apply to [sections 1 through ~~7~~ 6].

NEW SECTION. **Section 14. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

NEW SECTION. **Section 15. Contingent termination.** (1) [Section ~~10~~ 9] terminates on the date that the director of the department of public health and human services certifies to the governor that the federal government has terminated the program or that federal funding for the program has been discontinued.

(2) The governor shall transmit a copy of the certification to the code commissioner.

(3) Any excess funds remaining upon the termination of the program must be transferred to the general fund.

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